June 14, 2006

Mr. David H. Hinds, Manager, ESBWR
GE Nuclear Energy
PO Box 780, M/C L60
Wilmington, North Carolina 28402-0780

SUBJECT: NRC INSPECTION REPORT 05200010/2006-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Hinds:

On April 11-13, 2006, the U.S. Nuclear Regulatory Commission (NRC) conducted a follow-up inspection at the General Electric Nuclear Energy (GENE) facility in Wilmington, North Carolina. The purpose of the inspection was to review the GENE corrective action activities described in the GENE letter dated February 9, 2006, Reply to Notice of Nonconformance NRC Inspection Report 05200010/2005-201, that responded to the NRC Inspection Report 05200010/2005-201 and Notice of Nonconformance dated January 11, 2006. In addition to the follow-up of inspection findings identified during the November 2005 inspection, the NRC staff had discussions and reviewed the quality assurance (QA) program implementation of ESBWR Design Control Document (DCD) Chapter 17.4, "Reliability Assurance Program During Design Phase." The DCD Chapter 17.4 review used draft Standard Review Plan (SRP) Section 17.4 to support guidelines described in SECY-95-132, dated May 22, 1995, and SECY-94-084, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs." The enclosed report presents the details of the inspection.

During the inspection it was found that the implementation of your QA program failed to meet certain NRC requirements. GENE's corrective action processes have not been effective in addressing and correcting the root causes of nonconformances. Additionally, GENE did not adequately implement the requirements to process and complete corrective actions in a timely manner in accordance with the GENE QA program. Finally, it was identified that several ESBWR project documents, including certain DCD sections, have referenced editions of the ASME NQA-1 standard that are not consistent with DCD Chapter 17 QA program commitments. The specific findings and reference to the pertinent requirements are identified in the enclosures to this letter.

Two nonconformances are cited in the enclosed Notice of Nonconformance (NON) and are described in detail in the enclosed report. The NRC requests GENE to respond to the NON, and that GENE should follow the instructions specified in the enclosed NON when preparing its response.

Based on the NRC inspectors' review and discussions with GENE concerning the Reliability Assurance Program (RAP) during Design Phase, a number of missing details in DCD Section 17.4 and a lack of implementing procedures for the RAP were identified. The NRC staff will develop and issue requests for additional information (RAIs) separate from this inspection report. The GENE RAI responses will be documented in the staff's preliminary Safety Evaluation Report (PSER).

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.390, "Public Inspections, Exemptions, Requests for Withholding," of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room (PDR) or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA J. Calvo for:/

David B. Matthews, Director
Division of New Reactor Licensing
Office of Nuclear Reactor Regulation

Enclosures: 1. Notice of Nonconformance
2. Inspection Report 05200010/2006-201

Docket No. 52-010

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.390, "Public Inspections, Exemptions, Requests for Withholding," of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room (PDR) or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

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David B. Matthews, Director
Division of New Reactor Licensing
Office of Nuclear Reactor Regulation

Enclosures: 1. Notice of Nonconformance
2. Inspection Report 05200010/2006-201

Docket No. 52-010

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NOTICE OF NONCONFORMANCE

General Electric Nuclear Energy
Wilmington, North Carolina

Docket Number 05200010
Inspection Report Number 2006-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted April 11-13, 2006, of activities supporting General Electric Nuclear Energy's (GENE's) design certification for the economic simplified boiling water reactor (ESBWR), it appears that certain activities were not conducted in accordance with NRC requirements.

1. Criterion XVI, "Corrective Action," of 10 CFR Part 50, Appendix B, states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

   GENE Policy and Procedure (P&P) 70-11, "Quality Policy and Quality System Requirements," dated January 4, 2005, Section 8.15, describes the general requirements for implementation of a corrective action process including: (1) identification of the potential deficiency; (2) determination of the cause; (3) documenting recommended actions to correct deficiency; (4) documenting recommended actions to preclude recurrence; (5) and ensuring proper levels of management are made aware of the deficiency to achieve resolution.

   NEDO-11209-04A describes, in part, the general requirements for implementation of a corrective action program. Procedures and practices are established which provide assurance that conditions adverse to quality are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. Corrective action followup and closeout procedures provide for assuring that corrective action commitments are implemented in a systematic and timely manner.

   EOP 75-3.00, Revision 10, "Self-Assessment, Corrective Action, and Audits," dated May 12, 2005, specifies the responsibilities for actions to promptly identify, record and correct conditions adverse to quality and to assure that these conditions do not affect the quality of a product or service.

   Contrary to the above, GENE's corrective action process has not been effective at addressing and correcting the root causes of nonconformances. Additionally, GENE did not adequately implement the requirements to process and complete corrective actions in a timely manner in accordance with GENE QA program. This issue is identified as Nonconformance 05200010/2006-201-01.

2. Chapter 17, "Quality Assurance," of the ESBWR Design Control Document (DCD) describes the GENE QA program for the design and construction phase of the ESBWR program. Chapter 17 commits to meet the requirements of ANSI/ASME NQA-1-1983 and the NQA-1a-1983 addenda as endorsed by the NRC in Regulatory Guide 1.28,

Revision 3 (August 1985). Chapter 17 also references GE NEDO-33181, Revision 1 and NEDO-11209-04A, Revision 8.

NEDO-33181, Revision 1, dated October 2005, provides the QA system and the program description which GENE will implement as supplier of ESBWR engineering services for contractual requirements for Phase 1 and Phase 2 of the DOE NP-2010 COL (US NRC construction and operating license) Demonstration Project. This encompasses all quality related activities performed by GE, as well as those performed by its subcontractors during execution of the program.

NEDO-11209-04A is the QA program description that applies to all GENE activities performed affecting the quality of items and services supplied to nuclear power plants and establishes GENE's compliance with the provisions of Appendix B to 10 CFR 50. NEDO-11209-04A was in place for implementation of all previous simplified boiling water reactor (SBWR) design and test activities.

GENE Policy and Procedure (P&P) 70-11, “Quality Policy and Quality System Requirements,” dated January 4, 2005, defines the GENE quality policy, including the overall requirements for the Nuclear Energy business quality system. P&P 70-11, Section 8.2.1 states that Nuclear Quality Assurance (NQA) is responsible for developing, issuing, and maintaining P&P 70-11 and the QA Program description (NEDO-11209-04A). P&P 70-11, Section 8.4.2 requires that all safety-related products meet the applicable quality requirements of NEDO-11209 and the applicable licensing commitments.

Contrary to the above, during the review of Nonconformance 05200010/2005-201-02 and Unresolved Item (URI) 05200010/2005-201-01, the NRC inspectors identified that not all ESBWR project documents reference the appropriate ANSI/ASME NQA-1-1983 edition, as described and committed to in Chapter 17 of the ESBWR DCD. This issue has been identified as Nonconformance 05200010/2006-201-02.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, ESBWR/ABWR Projects Branch, Division of New Reactor Licensing, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to Notice of Nonconformance" and should include: 1) a description of steps that have been or will be taken to correct these items; 2) a description of steps that have been or will be taken to prevent recurrence; and 3) the dates your corrective actions and preventative measures were or will be completed.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. Agency-wide Documents Access and Management System (ADAMS) is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your

response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection, described in 10 CFR 73.21.

Dated this 14th day of June 2006.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION

Report No:	05200010/2006-201
Organization:	General Electric Nuclear Energy 3901 Castle Hayne Rd Wilmington, NC 28401
Vendor Contact:	Mr. David H. Hinds ESBWR Engineering Manager (910) 675-6363
Nuclear Industry:	General Electric Nuclear Energy (GENE) is engaged in the supply of advanced and standardized boiling water reactor (BWR) designs to utilities. GENE also furnishes engineering services, nuclear replacement parts, and dedication services for commercial grade electrical and mechanical equipment.
Inspection Dates:	April 11 -13, 2006
Inspectors:	Richard P. McIntyre, Lead Inspector, EQVA/DE/NRR Kerri A. Kavanagh, EQVA/DE/NRR Paul F. Prescott, EQVA/DE/NRR Frank Talbot, EQVB/DE/NRR Hien Le, EQVB/DE/NRR
Approved by:	Dale F. Thatcher, Chief Quality and Vendor Branch A Division of Engineering Office of Nuclear Reactor Regulation

1.0 INSPECTION SUMMARY

The purpose of the inspection was to review the General Electric Nuclear Energy (GENE) corrective action activities described in the GENE letter dated February 9, 2006, “Reply to Notice of Nonconformance NRC Inspection Report 05200010/2005-201,” that responded to the NRC Inspection Report 05200010/2005-201 and Notice of Nonconformance dated January 11, 2006.” In addition to the follow-up of the inspection findings identified during November 2005 inspection, NRC staff had discussions with GENE and reviewed the QA program implementation of the ESBWR Design Control Document (DCD) Chapter 17.4, “Reliability Assurance Program During Design Phase.”

The inspection was conducted at GENE's facility in Wilmington, North Carolina. The inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the Code of Federal Regulations (Appendix B), and

- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

1.1 REVIEW AND DISCUSSIONS CONCERNING THE ESBWR RELIABILITY ASSURANCE PROGRAM

The NRC inspection team reviewed GENE procedures and documents used to implement the Reliability Assurance Program (RAP) as described in GENE ESBWR DCD Section 17.4, “Reliability Assurance Program,” Revision 0. The staff used guidance from SECY 95-132, Item E, “Reliability Assurance Program,” SECY-94-084, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs,” and draft Standard Review Plan (SRP) Section 17.4, “Reliability Assurance Program (RAP).”

Using the above guidance, the NRC inspectors discussed in detail with GENE staff, the scope, purpose, and quality elements expected to be included in the GE ESBWR DCD Design RAP (D-RAP). Based on the NRC inspectors’ review and discussions, a number of missing details in DCD Section 17.4 and a lack of implementing procedures for the RAP were identified. The NRC inspectors will develop and issue requests for additional information (RAIs) separate from this inspection report, to GENE in the future. The GENE RAI responses will be documented in the staff’s preliminary Safety Evaluation Report (PSER).

1.2 NONCONFORMANCES

- Nonconformance 05200010/2006-201-01 was identified and is discussed in Section 3.5 of this report.

- Nonconformance 05200010/2006-201-02 was identified and is discussed in Section 3.2 of this report.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

Nonconformance 05200010/2005-201-01 (CLOSED)

During the previous inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure to implement the ESBWR design control process as required by the GENE QA program. During this inspection, the NRC inspectors reviewed the corrective and preventive actions associated with this nonconformance. This issue is further discussed in Section 3.1 of this report.

Nonconformance 05200010/2005-201-02 (CLOSED)

During the previous inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure of the GENE Nuclear Quality Assurance (NQA) external supplier audits to identify and audit/document against the appropriate QA program requirements (ANSI/ASME NQA-1-1983), consistent with Chapter 17 of the ESBWR DCD and the NEDO-11209-04A QA topical report. The NON also identified that GENE had not documented the completion of either the Corrective/Preventive Actions identification and the Response /Closure portions of the GENE CARs for certain supplier audit findings. During this inspection, the NRC inspectors reviewed the corrective and preventive actions associated with this nonconformance. This issue is further discussed in Section 3.2 of this report.

Nonconformance 05200010/2005-201-03 (CLOSED)

During the previous inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure to document and maintain training records in a centralized training database as required by the GENE QA program. During this inspection, the NRC inspectors reviewed the corrective and preventive actions associated with this nonconformance. This issue is further discussed in Section 3.3 of this report.

Nonconformance 05200010/2005-201-04 (CLOSED)

During the previous inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure to perform internal self-audits as required by the GENE quality assurance program. During this inspection, the NRC inspectors reviewed the corrective and preventive actions associated with this nonconformance. This issue is further discussed in Section 3.4 of this report.

Nonconformance 05200010/2005-201-05 (CLOSED)

During the previous inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure to complete the acceptance reviews associated with several ESBWR corrective action requests (CARs) within the 30 day period as required by the GENE quality assurance plan. Additionally, GENE did not complete the implementation of corrective actions associated with a number of ESBWR related CARs within the documented due dates or complete those corrective actions after the assigned due date. During this

inspection, the NRC inspectors reviewed the corrective and preventive actions associated with his nonconformance. This issue is further discussed in Section 3.5 of this report.

Unresolved Item 05200010/2005-201-01 (OPEN)

During the previous inspection, the NRC inspectors identified that Chapter 17 of the ESBWR DCD did not include an Introduction Section that describes what the ESBWR QA program is based upon and how it will be implemented by GENE and its various domestic and international participants. The NRC inspectors also noted that they were unable to review or verify the activities associated with the transition from the SBWR to ESBWR design, particularly as it relates to the qualification test activities that were performed for the SBWR design in the mid-1990s and are being used to support the ESBWR design certification application. GENE was requested to provide appropriate documentation in the DCD Chapter 17 Introduction Section describing the details of the QA program commitments and background information regarding the transition from the SBWR to ESBWR design. This issue is further discussed in Section 3.6 of this report.

This issue will remain OPEN pending completion of the corrective actions described in Section 3.6 of this report.

Unresolved Item 05200010/2005-201-02 (OPEN)

During the previous inspection, the NRC inspectors discussed the need to recapture the design and test control implementation inspection documentation issued by the NRC staff for the SBWR design certification qualification testing activities which are being used to support ESBWR design certification. This documentation includes all NRC Inspection Reports, GENE responses to inspection findings, and NRC replies to GENE responses. GENE was requested to recapture this SBWR inspection documentation for inclusion in the ESBWR Chapter 21 FSER for Quality Assurance Inspections related to Testing and Computer Code Evaluation. This issue is further discussed in Section 3.7 of this report.

This issue will remain OPEN pending completion of the corrective actions described in Section 3.7 of this report and as discussed with GENE staff during this inspection.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 05200010/2005-201-01

a. Inspection Scope

The NRC inspection team reviewed GENE corrective and preventive actions associated with Nonconformance 05200010/2005-201-01, which was identified during the November 15-17, 2005, NRC inspection.

b. Observations and Findings

During the November 2005 inspection, the NRC inspectors identified a nonconformance with respect to GENE's implementation of the design control process as required by the GENE

quality assurance program. Specific examples that supported the nonconformance included the following: (1) a letter was not prepared documenting the revised completion date of the ESBWR Design Control Document (DCD) verification when the schedule was not met; (2) the work plan/detailed schedule for the ESBWR project was not maintained or updated; and (3) design and verification documentation was not complete prior to ESBWR DCD design verification. Corrective Action Request (CAR) 40517 was initiated by GENE to address the nonconformance and to address actions to preclude recurrence. CAR 40517 stated that the root cause of this nonconformance was due to staff oversight and resource pressures and constraints.

b.1 Design Verification Deferral

Corrective action number 1 of CAR 40517 required the issuance of a letter to document the revised completion dated of the DCD verification. In a letter dated November 22, 2005 (MFN 05-139), GENE provided to the NRC the revised dates to remove the conditional release from the DCD. An additional letter, dated January 16, 2006 (MFN 06-015), was submitted to the NRC to further update removal of a portion of the conditional release. The NRC inspectors reviewed the two letters and GENE Engineering Operating Procedure (EOP) 42-6.10, Revision 6, "Deferred Design Verifications," which defines the processes for deferring design verification and for clearing previous deferrals. The NRC inspectors concluded that the GENE letters met the intent of EOP 42-6.10 and completed the corrective action. However, the NRC inspectors identified that GENE did not correctly follow the remaining steps of the EOP. Specifically,step 4.2.3 of EOP 42-6.10 requires GENE to "store the approved archive format letter in the DRF associated with the ERM/ECN in a file object whose title starts with "Deferred Verification Modification.'" The NRC inspectors and a member of ESBWR engineering reviewed the design record files (DRFs) associated with Revision 0 and Revision 1 of the DCD, and concluded that neither MFN 05-139 nor MFN 06-015, was included in either DRF. Discussions with GENE licensing revealed that all MFNs are stored in the Regulatory Service Letters library and not in DRFs. At the time of the inspection exit, GENE had committed to capture MFN 05-139 and MFN 06-015 in the appropriate DRFs.

The NRC inspectors also reviewed the preventive action associated with corrective action number 1, which entailed reviewing CAR 40517 with all ESBWR design engineers to stress the importance of referencing appropriate supporting documentation, and reviewing the verification process. The NRC inspectors reviewed the email sent to all ESBWR design engineers that discussed CAR 40517, EOP 42-1.00, "Design Process," and EOP 42-6.00, "Independent Design Verification." The email specifically requested all ESBWR design engineers to: (1) review EOP 42-1.00 and 42-6.00 and update their training records in the GENE Training Database, and (2) review the ESBWR DRFs to confirm that all necessary critical thinking, logic, and complete supporting references are documented. These actions were to be completed prior to March 31, 2006. During the inspection, the NRC inspectors identified that four ESBWR engineers had not completed training on EOP 42-1.00 and five ESBWR engineers had not completed training on EOP 42-6.00. At the time of the inspection exit, GENE had committed to completing the training associated with the preventive action.

b.2 Work Plan and Project Schedule

Corrective action number 2 of CAR 40517 required the revision of the Work Plan for ESBWR licensing and construction to document customer or internally initiated changes. NEDE-33273, Revision 1, "NP-2010 COL Demonstration Project - Project Work Plan," was dated March 2006, and was made a training requirement for all ESBWR staff. The NRC inspectors reviewed NEDE-33273 Revision 1, and concluded that the revision completed the corrective action. The NRC inspectors identified that although NEDE-33273, Revision 1, was available on the ESBWR shared folder (M drive), it was not released and available for use in DRF 0000-0035-5360. The NRC inspectors were informed that the procedure was not clear as to when the DRF had to be updated to show the released documents. The NRC inspectors verified that NEDE-33273, Revision 1, was released in the DRF during the inspection.

Corrective action number 3 of CAR 40517 required the creation of a Phase II Project schedule which included a master engineering schedule and COL schedule. The NRC inspectors verified that a full project master engineering schedule with resource loading was created to provide all participants the detailed engineering schedule, with oversight reviews at appropriate intervals. This master engineering schedule is updated on a monthly basis, whereas the COL schedule is updated weekly. The NRC inspectors discussed the master engineering schedule and the COL schedule with the Project Office schedulers who meet regularly with the ESBWR managers and leads to ensure that the schedules adequately represent progress, status and changes to the schedules. The NRC inspectors concluded that the master engineering schedule and COL schedule adequately completed the corrective action.

b.3 Design Process and Verification

Corrective action number 4 of CAR 40517 required action to ensure that the appropriate supporting documents are listed for the isolation condenser system (ICS) design. The NRC inspectors discussed corrective action number 4 with the responsible manager of the safety-related systems and confirmed that GENE understood that the NRC nonconformance example of inadequate supporting documentation was not limited to the ICS. The GENE representative informed the NRC inspectors that, at the time of the inspection, all safety-related systems had at least one supporting document (e.g., the subject system's piping and instrumentation diagram (P&ID), process flow diagram (PFD), and logic diagram [LD]) listed in the system design specification. The NRC inspectors concluded that the completion of the minimum supporting documentation for all safety-related system design specifications completed the corrective action.

The NRC inspectors also reviewed the preventive action associated with corrective action number 4 which entailed increasing the ESBWR staffing level to ensure adequate focus on proper design controls and processes. As of April 2006, GENE has almost doubled the GE engineering employees (44 versus 28) assigned to the project. In addition, GENE has 24 full-time dedicated contractors along with several off-site employees supporting the project through other engineering firms.

c. Conclusions

The NRC inspectors reviewed the corrective and preventive actions associated with GENE CAR 40517 regarding GENE's implementation of the design control process as required by the GENE quality assurance program. As described above, GENE issued a letter to the NRC dated November 22, 2005, to document the revised completion dated of the DCD verification, revised the Work Plan for ESBWR licensing and construction to document customer or internally initiated changes, created a Phase II Project schedule which included a master engineering schedule and COL schedule, and ensured that the appropriate supporting documents are listed for the isolation condenser system (ICS) design. The NRC inspectors concluded that the corrective actions were complete and closed Nonconformance 05200010/2005-201-01.

3.2 REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 05200010/2005-201-02

a. Inspection Scope

The NRC inspection team reviewed GENE corrective and preventive actions associated with Nonconformance 05200010/2005-201-02, which was identified during the November 15-17, 2005, NRC inspection.

b. Observations and Findings

During the November 2005 inspection, the NRC inspectors identified a nonconformance with respect to GENE's implementation for oversight of safety-related suppliers for the ESBWR program. The NRC inspectors identified several examples where the process of controlling purchased engineering services for the ESBWR program were not implemented in accordance with GENE procedures. These examples included: (1) GENE failure to identify the appropriate QA program requirements that conformed to GE ESBWR DCD Chapter 17 and NEDO-11209-04A; and (2) GENE had not documented the completion of either the Corrective/Preventive Actions identification and the Response /Closure portions of the GENE CARs for supplier audit findings at Black and Veatch Corporation; Empresarios Agrupados Internacional, S.A.; and Shimizu Corporation.

The NRC inspectors reviewed CAR 40518 that was initiated by GENE to address the nonconformance and to address actions to preclude recurrence. The root cause of this nonconformance was identified as failure to properly communicate between organizations that NQA-1-1983 was the standard edition that was committed to in the ESBWR DCD Chapter 17. During an internal audit of the ESBWR project performed in January 2005, the industry standard identified to be applicable to the ESBWR project was NQA-1-2000. The audit team discussed that NQA-1- 2000 had never been accepted by the NRC and was incorrect for application to the ESBWR. However, when the DCD was submitted later in August 2005, Chapter 17 committed to NQA-1-1983 and this information had never been properly communicated between Nuclear Quality Assurance and the ESBWR project. During review and follow-up of the 3 suppliers mentioned above that had been utilized for the ESBWR project, GENE concluded that even though the supplier audits had not identified the correct quality programs to audit against, the 3 suppliers were implementing NQA-1-1983 quality programs or

had programs determined by GENE to be equivalent to NQA-1-1983. Based on the review of the above information this closes out the first portion of the NON.

During the inspection, the NRC inspectors discussed with GENE the identification of the appropriate QA DCD Chapter 17 program requirements in ESBWR project documents other than NQA Audit Reports. The inspectors also identified other DCD sections that referenced other editions of the NQA-1 standard not consistent with DCD Chapter 17 QA program commitments. This included Tables within Section 3 of the DCD.

NEDO-33181, Revision 1, "NP-2010 COL Demonstration Project - Quality Assurance Plan," dated October 2005, provides the QA system and the program description which GENE will implement as supplier of ESBWR engineering services for contractual requirements for Phase 1 and Phase 2 of the DOE NP-2010 COL (US NRC construction and operating license) Demonstration Project. This document includes Table 1, which is a comparison of QA standards and compares 10CFR50, Appendix B, with ANSI/ASME NQA-1-1994, instead of NQA-1-1983. Also, NEDC-33260, Revision 0, "NP-2010 COL Demonstration Project - Supplier Quality Assurance Requirements (SQAR) - ESBWR QA Requirements for Procurement of Engineering Services and Equipment," dated January 2006, does not reference QA program requirements consistent with ESBWR DCD Chapter 17.

In response to this issue, GENE opened CAR 40911 during the inspection, to determine which ESBWR project documents need to be revised to reflect the DCD commitment to NQA-1-1983 edition. The CAR identified that as a minimum, the following documents need to be reviewed: DCD sections (as appropriate); Project QA plan (NEDO-33181, Revision 1) and ESBWR SQAR (NEDC 33260, Revision 0). The CAR also documents to revise purchase orders that imposed the SQAR to specify NQA-1-1983 edition, and also to ensure that ESBWR staff is aware of the appropriate QA program commitment.

The above failure to identify QA program requirements consistent with the ESBWR DCD Chapter 17 commitments is identified as Nonconformance 05200010/2006-201-02.

Concerning the second part of the NON for failure to document completion of the corrective actions described for audit findings, the NRC inspectors determined that since the November 2005 inspection, GENE has received and accepted the CAR responses for the Empresarios Agrupados Internacional audit findings. For Black & Veatch, GENE has since received all of responses for the open CARS and accepted five of the seven responses. The remaining two CARS still have open actions that need to be completed by Black & Veatch. As far as Shimizu is concerned, GENE had planned to review and accept the open CARS from the June 2005 GENE audit. However, during the March 2006 audit, GENE was unable to accept six of the nine open CARS and identified additional findings and opened nine new audit CARS during the audit at Shimizu.

The NRC inspectors also noted that the March 2006, Shimizu Audit Report identified, but did not discuss or describe the nature of the remaining open audit finding CARS or why they still remain open. Based on the fact that nine new audit CARS were identified, it would appear that there should be a real concern with Shimizu QA program implementation for closing of previous audit finding CARS.

Based on the results of this review, the NRC inspectors are identifying this issue as part of a new nonconformance, Nonconformance 05200010/2006-201-01, for ineffective and untimely corrective actions in accordance with the GENE quality assurance program and as identified and described in Section 3.5 of this inspection report.

c. Conclusions

The NRC inspectors reviewed the corrective and preventive actions associated with GENE CAR 40518 regarding GENE's implementation for oversight of safety-related suppliers for the ESBWR program. The NRC inspectors concluded that the corrective actions were completed as stated in the CAR, but that Shimizu and Black & Veatch still have open CARS associated with audit findings from June and September 2005 GENE NQA audits at their facilities.

As a result of this review, the NRC inspectors have CLOSED Nonconformance 05200010/2005-201-02. However, issues related to effectiveness and timeliness for corrective actions for previous audit findings CARS are included as part of a new nonconformance, Nonconformance 05200010/2006-201-01 as identified and described in Section 3.5 of this inspection report.

Also, since all ESBWR project documents did not reference the appropriate ASME NQA-1-1983 edition, as described and committed to in Chapter 17, Quality Assurance, of the ESBWR DCD, this was treated as a new nonconformance, Nonconformance 05200010/2006-201-02.

3.3 REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 05200010/2005-201-03

a. Inspection Scope

The NRC inspection team reviewed GENE corrective and preventive actions associated with Nonconformance 05200010/2005-201-03, which was identified during the November 15-17, 2005, NRC inspection.

b. Observations and Findings

During the November 2005 inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure to document and maintain training records in a centralized training database as required by the GENE QA program. CAR 40519 was initiated by GENE to address the nonconformance and to address actions to preclude recurrence. CAR 40519 stated that the root cause of this nonconformance was due to a lack of management follow-through to implement the EOP 75-5.00, Revision 13, "Quality and Technical Training," requirement to record training requirements and training completion in a centralized training database.

Corrective action number 1 of CAR 40519 required that the GENE Training Database be updated to account for the full ESBWR roster and their individual training requirements. Corrective action number 2 of CAR 40519 required notification of all ESBWR staff to update training requirements in the GENE Training Database and established a 30-day commitment to complete the required training. The NRC inspectors reviewed the GENE Training Database and the memo sent to all ESBWR employees instructing them to update and complete their

required training. The NRC inspectors concluded that GENE had completed corrective action numbers 1 and 2.

Corrective action number 3 of CAR 40519 required the ESBWR manager to review all ESBWR staff training records in the GENE Training Database to ensure that the staff had completed all required training per corrective actions 1 and 2 of CAR 40519. The due date for completion of this review was April 14, 2006, one day after the exit of the NRC inspection. The NRC inspectors were shown two screens within the GENE Training Database; one screen tracked the completed training for each employee, the other screen tracked the training not completed for each employee. The GENE Training Database did not differentiate between existing ESBWR staff and new ESBWR staff. The NRC inspectors were unable to determine who had training to complete that were existing ESBWR staff members. Based on the NRC inspectors review of the GENE Training Database, the NRC inspectors could not conclude that this activity would be complete by the due date due to the number of ESBWR staff that still needed to complete the required training. The NRC inspectors noted that this concern was also documented in the GENE internal self-audit of the ESBWR program described in section 3.4 of this report.

The NRC inspectors also reviewed CAR 20380 that was initiated on August 10, 2005, regarding the same issue as NRC Nonconformance 05200010/2005-201-03. The corrective action associated with CAR 20380 required all ESBWR staff to update the GENE Training Database to be consistent with the training requirements maintained in the ESBWR engineering spreadsheet and to show proper completions. The corrective action was complete on November 30, 2005, and CAR 20380 was closed on December 13, 2005.

The NRC inspectors reviewed the preventive actions associated with CARs 40519 and 20380, requiring ESBWR staff to review EOP 75-5.00. The NRC inspectors determined that the preventive actions taken as a result of CARs 40519 and 20380 do not prevent the failure to maintain the GENE Training Database beyond the April 14, 2006, completion date of corrective action number 3 of CAR 40519.

c. Conclusions

The NRC inspectors reviewed the corrective and preventive actions associated with GENE CAR 40519 associated with failure to document and maintain training records in a centralized training database as required by the GENE QA program. The NRC inspectors concluded that the corrective actions were completed as stated in the CAR, except for one which was not scheduled to be completed at the time of the inspection, and closed Nonconformance 05200010/2005-201-03.

3.4 REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 05200010/2005-201-04

a. Inspection Scope

The NRC inspection team reviewed GENE corrective actions associated with Nonconformance 05200010/2005-201-04, which were identified during the November 15-17, 2005, NRC inspection.

b. Observations and Findings

During the November 2005 inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure to perform internal self-audits as required by the GENE QA program. Specifically, the 2005 schedule of internal audits did not reflect the ESBWR program, and at the time of the inspection, no internal audits were planned or scheduled for the remainder of 2005. CAR 40520 was initiated by GENE to address the nonconformance and to address actions to preclude recurrence. CAR 40520 stated that the root cause of this nonconformance was due to a transition between line quality managers during the 2005 Audit Planning Cycle. As a result, the internal self audit of the ESBWR program was omitted from both quality organizational audit schedules.

Corrective action number 1 of CAR 40520 required that the ESBWR self-audit be included in the 2006 GE Nuclear Internal Audit Plan and be completed in the first quarter of 2006. Corrective action number 2 of CAR 40520 required the ESBWR self-audit to be performed. The NRC inspectors reviewed the 2006 GE Nuclear Internal Audit Plan and confirmed that the ESBWR self-audit was planned and scheduled to be completed by March 31, 2006. GENE performed the self-audit (GEN 06-13) the week of March 27, 2006, which assessed the adequacy, effectiveness and implementation of the GENE QA Program for ESBWR design activities. The NRC inspectors reviewed the audit report dated April 10, 2006, which identified three deficiencies, two recommendations and two concerns. One deficiency regarding ineffective corrective/preventive actions addressing CAR timeliness is discussed further in section 3.5 of this report. Based on the above, the NRC inspectors concluded that the corrective actions were complete for CAR 40520.

c. Conclusions

The NRC inspectors reviewed the corrective actions associated with CAR 40520 regarding GENE's failure to conduct an internal self-audit in 2005. As described above, GENE planned and conducted an internal self-audit of the ESBWR project in the first quarter of 2006. The NRC inspectors concluded that the corrective actions were complete and closed Nonconformance 05200010/2005-201-04.

3.5 REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 05200010/2005-201-05

a. Inspection Scope

The NRC inspection team reviewed GENE corrective and preventive actions associated with Nonconformance 05200010/2005-201-05, which was identified during the November 15-17, 2005, NRC inspection.

b. Observations and Findings

b.1 CAR 40521

During the November 2005 inspection, the NRC inspection team identified a nonconformance with NRC requirements associated with failure to complete the acceptance reviews associated with several ESBWR CARs within the 30 day period as required by the GENE QA plan. GENE

did not complete the implementation of corrective actions associated with a number of ESBWR related CARs within the documented due dates or complete those corrective actions after the assigned due date.

CAR 40521 was initiated by GENE to address the nonconformance and to address actions to preclude recurrence. CAR 40521 stated that the root cause of this nonconformance was due to resource pressure and management priorities during the DCD preparation. Corrective action number 1 of CAR 40521 required that the ESBWR manager assign an ESBWR responsible engineer to track CAR process and actions and to drive timely closure of CARs. Corrective action number 2 of CAR 40521 required the assignment of one or more ESBWR QA engineer(s) to track CAR process and actions and drive timely closure by ESBWR-related staff. The NRC inspectors met with both ESBWR Engineering and QA engineers to determine their role and effectiveness in managing the close out of ESBWR CARs. These individuals are part of the CAR performance initiative and they are available to assist ESBWR staff with the timely completion of their CARs, if requested. The NRC inspectors discussed a preventive action to CAR 40521 which established regular CAR status meetings between the ESBWR manager and the ESBWR responsible engineer, to discuss the status of ESBWR CARs.

The GENE internal self-audit of the ESBWR program described in section 3.4 of this report documented a deficiency specifically on CAR 40521. The audit report concluded that based on the number of passed due actions that still exist with ESBWR CARs, the corrective and preventive actions specified in CAR 40521 have not been effective in improving timeliness.

In addition, the NRC inspectors identified that CAR 40521 was closed on March 29, 2006. The closure of this CAR was not consistent EOP 75.3-00, Revision 10, “Self-Assessment, Corrective Action, and Audits.” Specifically step 4.4.10 of EOP 75-3.00 instructs the acceptance of the CAR for closure in the CTS. However, a note to step 4.4.10 states “CAR closure of an External (External Audit or External Non-audit) CAR is contingent upon the concurrence of the customer, regulatory authority or other external organization.” Per the GENE internal self-audit report, the ESBWR team will determine revised actions to address the ineffectiveness of the corrective and preventive actions associated with CAR 40521. These revised actions will be documented and tracked under the existing CAR 40521.

b.2 Corrective Actions

NEDO-11209-04A is the QA program description that applies to all GENE activities performed affecting the quality of items and services supplied to nuclear power plants and establishes GENE's compliance with the provisions of Appendix B to 10 CFR 50. NEDO-11209-04A describes, in part, the general requirements for the implementation of a corrective action program. Procedures and practices are established which provide assurance that conditions adverse to quality are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. Corrective action followup and closeout procedures provide for assuring that corrective action commitments are implemented in a systematic and timely manner.

GENE Policy & Procedure 70-11, "Quality Policy and Quality System Requirements," Section 8.15, describes the general requirements for implementation of a corrective action process. Section 8.18 requires periodic review of the quality management system to ensure suitability, adequacy, and effectiveness.

EOP 75-3.00 specifies the responsibilities for actions to promptly identify, record and correct conditions adverse to quality and to assure that these conditions do not affect the quality of a product or service. CARs are tracked in the electronic commitment tracking system (CTS 4) and contains the official quality records assigned for each CAR.

The NRC inspectors reviewed CAR 40274 which was initiated on November 11, 2005. The CAR 40274 problem description stated that a CTS 4 snapshot on November 11, 2005 revealed over 100 internal CARs with overdue responses (ranging from 1 to 3627 days) and over 25 external CAR overdue responses (ranging from 3 to 721 days). Overdue CAR responses is a violation of EOP 75-3.00. CAR 40274 was generic to all GENE business segments and stated that the root cause was inadequate oversight of the implementation of the corrective action process. Corrective action number 2 of CAR 40274 required the Quality Assurance Manager to send a memo to all business segment managers to require them to self-initiate a CAR, as per EOP 75-3.00 to investigate and to take appropriate corrective and preventive actions to address the issue of overdue CAR responses in their respective business segments. Corrective action number 2 was complete on January 5, 2006.

Corrective action number 3 of CAR 40274 required the Manager of Engineering to self-initiate an internal CAR to investigate and develop corrective and preventive actions to address the issue of overdue CAR responses. The goal was to clear the backlog of all overdue CAR responses in Engineering by March 31, 2006, to meet the 30-day requirement to complete the responses to all the new CARs. The due date for corrective action number 3 was March 31, 2006. The NRC inspectors noted that there was no evidence that this corrective action was completed at the time of the inspection exit. However, CAR 40274 indicated that the managers of the other business segments completed the identical corrective action for their business segments by the March 31, 2006 due date.

During the inspection of the corrective preventive actions for the nonconformances identified in the November 2005 inspection, the NRC inspectors noted a trend in the documentation of the root cause of the nonconformances. Specifically, the CARs cited 1) resource pressures and constraints, 2) lack of management follow-through, 3) management priorities, and 4) inadequate oversight as the root causes of the majority of the CARs reviewed by the NRC inspectors. The failure of the Manager of Engineering to self-initiate an internal CAR (as per CAR 40274) to investigate and develop corrective and preventive actions to address the issue of overdue CAR responses appears to be a good example of these root causes. In addition, the NRC inspectors could not conclude that the corrective and preventive actions adequately address the root cause of the original nonconformances. As a result, the NRC inspectors determined that the requirements to process and complete corrective actions were not adequately implemented in a timely manner in accordance with GENE quality assurance program. This issue has been identified as Nonconformance 05200010/2006-201-01.

c. Conclusions

The NRC inspectors reviewed the corrective and preventive actions associated with CAR 40521 associated with failure to complete the acceptance reviews associated with several ESBWR CARs within the 30 day period as required by the GENE quality assurance plan and the implementation of corrective actions associated with a number of ESBWR related CARs within the documented due dates. As a result of corrective actions completed as stated in the CAR, the NRC inspectors closed Nonconformance 05200010/2005-201-05.

Based on the examples cited above and the results of the GENE internal self-audit, the NRC inspectors concluded that the GENE corrective action process has not been effective at addressing and correcting the root causes of nonconformances. The NRC inspectors determined that the requirements to process and complete corrective actions were not adequately implemented in a timely manner in accordance with the GENE QA program. This issue has been identified as new Nonconformance 05200010/2006-201-01.

3.6 REVIEW OF CORRECTIVE ACTIONS - UNRESOLVED ITEM 05200010/2005-201-01

a. Inspection Scope

The NRC inspection team reviewed GENE corrective actions and response associated with Unresolved Item 05200010/2005-201-01, which was identified during the November 15-17, 2005, NRC inspection.

b. Observations and Findings

During the November 2005 inspection, the NRC inspectors identified an Unresolved Item identifying that Chapter 17 of the ESBWR DCD did not include an Introduction Section that describes what the ESBWR QA program is based upon and how it will be implemented by GENE and its various domestic and international participants. The NRC inspectors also noted that they were unable to review or verify the activities associated with the transition from the SBWR to ESBWR design, particularly as it relates to the qualification test activities that were performed for the SBWR design in the mid-1990s and are being used to support the ESBWR design certification application. GENE was requested to provide appropriate documentation in the DCD Chapter 17 Introduction Section describing the details of QA program commitments and background information regarding the transition from the SBWR to ESBWR design.

CAR 40522 was initiated by GENE to address actions to be taken to reply to the unresolved item. Two corrective actions were identified in the CAR to be completed by GENE. The NRC inspectors verified by review of Revision 1 of Chapter 17 of the ESBWR DCD that an Introduction Section was included in Chapter 17 that describes the QA program used by GENE for the ESBWR project.

Corrective action # 2 listed on the CAR required GENE to prepare a revision to the DCD to provide a description of the design transition and use of the SBWR Test Program. This action has not yet been completed or incorporated into the ESBWR DCD. Therefore, Unresolved Item 05200010/2005-201-01 will remain OPEN pending completion of corrective action # 2 as described in CAR 40522.

c. Conclusions

The NRC inspectors determined that Unresolved Item 05200010/2005-201-01 will remain OPEN pending completion of corrective action # 2 as described in CAR 40522.

3.7 REVIEW OF CORRECTIVE ACTIONS - UNRESOLVED ITEM 05200010/2005-201-02

a. Inspection Scope

The NRC inspection team reviewed GENE corrective actions and response associated with Unresolved Item 05200010/2005-201-02, which was identified during the November 15-17, 2005, NRC inspection.

b. Observations and Findings

During the November 2005 inspection, the NRC inspectors identified an Unresolved Item identifying the need to recapture the design and test control implementation inspection documentation issued by the NRC staff or GENE for the SBWR design certification qualification testing activities which are being used to support ESBWR design certification. As part of the SBWR design certification review, the staff conducted in-depth inspections at the principal GENE SBWR test facilities to determine if these testing activities performed to support design certification of the SBWR were conducted under the appropriate provisions of the NEDO-11209-04A, Revision 8 and NEDG-31831, "SBWR Design and Certification Program Quality Assurance Plan," dated May 1990. SBWR design certification qualification testing activities were conducted by GENE at test facilities such as the PANDA test facility in Switzerland, the PANTHERS test facility in Italy, and the GIRAFFE test facility in Japan.

The data from these qualification testing activities is being used to support ESBWR design certification. This documentation should include all NRC Inspection Reports, GENE responses to inspection findings, and NRC replies to GENE responses. GENE was requested to recapture this SBWR inspection documentation for inclusion in the ESBWR Chapter 21 Final Safety Evaluation Report (FSER) for Quality Assurance Inspections related to Testing and Computer Code Evaluation.

CAR 40523 was initiated by GENE to address actions to be taken to reply to the Unresolved Item. During the inspection, GENE stated that they had attempted to identify DRF files associated with SBWR testing activities and include it on a data base. Unfortunately, this data base included all documentation associated with the SBWR test programs, and went well beyond the QA program implementation inspections related to SBWR. The NRC inspectors and GENE staff reviewed the database and tried to identify the documentation that would fit the search criteria. GENE committed to review the highlighted database and identify the inspection documentation needed for the NRC staff to adequately document and describe the design and test control implementation inspection activities in support of Chapter 21 of the ESBWR FSER.

Therefore, Unresolved Item 05200010/2005-201-02 will remain OPEN pending completion of the corrective action described in CAR 40522 and as per discussions with the NRC inspectors during the inspection.

c. Conclusions

The NRC inspectors determined that Unresolved Item 05200010/2005-201-02 will remain OPEN pending completion of the corrective action described in CAR 40522 and as per discussions with the NRC inspectors during the inspection.

4.0 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on April 11, 2006, the NRC Inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with GE staff and management. In the exit meeting on April 13, 2006, the NRC Inspectors discussed the inspection results and findings with GE management and staff.

5.0 PARTIAL LIST OF PERSONS CONTACTED

Tammy Orr	Manager, GE Quality	GE	**
David Hinds	Manager, ESBWR Engineering	GE	**
Russell Bastyr	Manager, Quality Systems & Services	GE	**
Allen Dubberley	ESBWR Engineering	GE	**
Jason Post	Manager, Engineering Processes	GE	**
Rick Kingston	Project Manager, Dominion	GE	*
Wayne Marquino	ESBWR Engineering	GE	**
Rick Wachowiak	ESBWR PRA	GE	*
Jerry Deaver	ESBWR Comp & Sys Lead	GE	**
Paul Ragan	ESBWR Engineering	GE	**
James Jackson	ESBWR QA	GE	**
Stephan Mindel	ESBWR QA	GE	**
Isreal Nir	Manager, Technical Training	GE	**
George Stramback	Licensing	GE	***
Louis Quintana	Manager, Licensing	GE	****
Larry Fennern	ESBWR	GE	****
Paul Sick	Quality Assurance	GE	

* Attended Entrance Meeting
** Attended Entrance & Exit Meeting
*** Teleconference for Exit Meeting
**** Attended Exit Meeting